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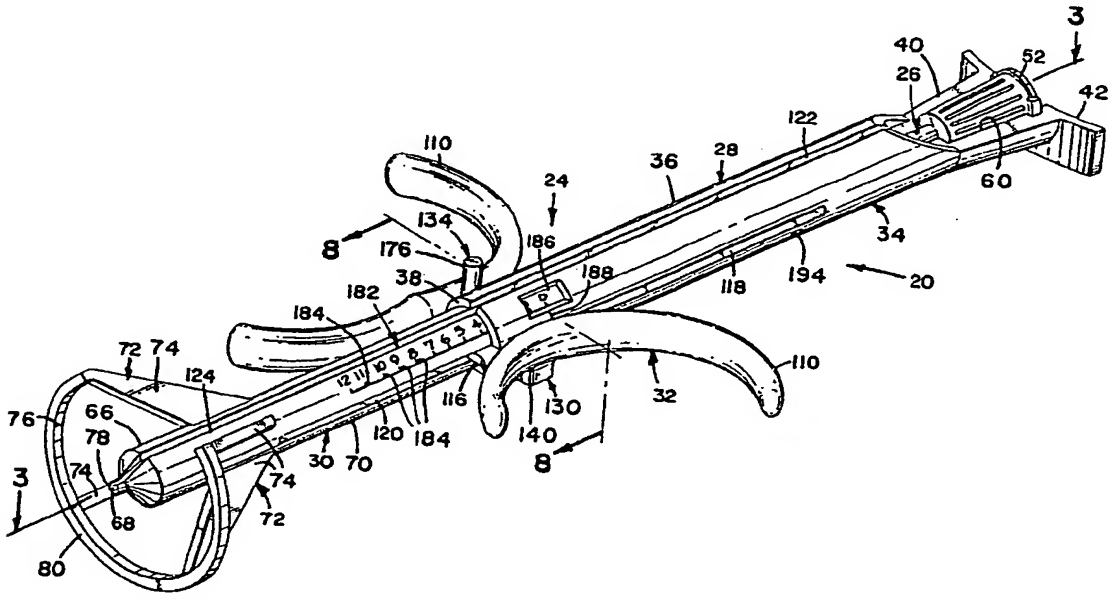

(57) Abstract

The applicator (24) combined with a splittable cannula (22) functions to place a catheter (26) through a body membrane and then separate from the catheter (26) leaving the catheter in place and allowing for disposal of the applicator and cannula. The catheter is supported during placement. The cannula is completely contained within the applicator except when the distal end is inserted through the body membrane. Depth of insertion is readily monitored.

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APPLICATOR WITH SPLITTABLE CANNULA FOR PLACEMENT OF FLEXIBLE CATHETER

Field of the Invention

The present invention relates to medical devices and, in particular, to a cannula and an applicator which support a catheter during insertion of an end of the catheter through a body membrane of a person or animal.

Background of the Invention

Many presently known medical treatments require the placement of one end of a flexible catheter through a body membrane, usually the skin. Such medical treatments are appropriate for most humans and animals. Known catheter placement units use a cannulated needle to provide a guide for the flexible catheter. After the catheter is placed, the needle is withdrawn. Sometimes, the needle is not removed from the catheter, but rather is taped to it. Although the sharpened end of the needle is usually covered with tape, this method is rather crude and not particularly sanitary.

U. S. Patent 3,262,449 shows a catheter placement unit having a housing with a sheath into which the needle may be drawn and contained. The housing is not separable from the catheter, however, and, although it would appear to be safer and more sanitary than the method indicated above, this placement unit still suffers from being cumbersome and requires careful handling of the housing.

A more desirable method is shown in U. S. Patent 3,359,978, U. S. Patent 4,377,165, and U. S. Patent 4,449,973. In each of these patents, there is shown a cannulated needle which may be split or broken in order to remove it from the catheter once the catheter is placed. Although these various needles solve the primary problem of the earlier mentioned methods, that is, removable of the needle from the catheter once it is placed, they continue to

lack a number of features desirable for most medical procedures which require catheter placement. For example, the sharpened end of the needle is always exposed leading to the possibility of accidental puncture and resultant infection of a doctor or nurse. The disclosed needles support only a portion of the catheter thus requiring the unsupported portion to be held by a second hand or another person. None of the disclosed needles provides for structure to stabilize the insertion process and to control insertion angle and depth. The present invention not only is separable from the catheter after placement of the catheter, but also provides for these and other features.

Summary of the Invention

The present invention is directed to apparatus for inserting a catheter through a body membrane of a person or an animal. The apparatus includes a mechanism for supporting the catheter during insertion wherein the supporting mechanism includes a pointed cannula for piercing the membrane. The apparatus further includes a mechanism for stabilizing the supporting mechanism with respect to the membrane.

In another embodiment, the apparatus includes a splittable cannula for receiving the distal end portion of the catheter. The distal end of the cannula is sharpened to pierce the membrane. The apparatus of this embodiment is particularly advantageous since it includes mechanism for containing the cannula both before insertion into the membrane and after retraction therefrom. The containing mechanism includes a passageway through which the catheter and cannula move. The containing mechanism further includes a mechanism for splitting the cannula on retraction. In addition, the apparatus of this embodiment has a mechanism connected to the containing mechanism for moving the cannula with respect to the passageway so that the cannula and catheter may be advanced during insertion and so that the

cannula may be moved in a reverse direction against the splitting mechanism on retraction. Advantageously, the apparatus also provides separating mechanism so that the cannula, the containing mechanism and the moving mechanism may be separated from the catheter after the splitting of the cannula.

Another particularly advantageous feature of the invention recognizes that the stabilizing mechanism establishes a reference. The apparatus then includes a further depth indicating mechanism for controlling depth of insertion of the cannula and catheter relative to the reference.

The cannula of the present invention is also novel. The cannula comprises a member having a hollow, elongated tubular portion. The distal end portion of the tubular portion is sharpened to facilitate piercing the membrane. The tubular portion also includes a plurality of axially extending separable joints. At the proximal end, the tubular portion forms a conical seat for receiving an unattached cone-shaped end of a splitter element of the applicator. The proximal end portion of the cannula extends from the conical seat to form a mechanism for connecting to the applicator. With this configuration, movement of the tubular-like element of the applicator with respect to the cone-shaped seat of the cannula causes the tubular portion of the cannula to split at the separable joints thereby allowing easy removal of the catheter from the cannula.

The method of using the present invention is new. The method includes the steps of placing the stabilizing mechanism on the person or animal. The distal ends of the cannula and the catheter are then inserted through the body membrane by moving the cannula with moving mechanism. The cannula is next retracted. The cannula and the applicator are then separated from the catheter thereby leaving the

catheter in place through the membrane of the person or animal.

The apparatus and method are controllable, safe, and lead to the complete separation of the apparatus from the catheter when placement is complete. In addition, the apparatus of the present invention is applicable to numerous types of catheter placements, including for example transcutaneous, epidural, intravascular, intramuscular, intrathecal, intracerebroventricular, stereotactic, or into any specific body site or chamber.

These objects and advantages of the present invention having been summarized may be better understood by reference to the drawings briefly described hereinafter and to the detailed description of the preferred embodiment following subsequently.

Brief Description of the Drawings

FIGURE 1 is a perspective view showing the pre-insertion configuration of an apparatus in accordance with the present invention;

FIGURE 2 is a rear, plan view of the apparatus of FIGURE 1;

FIGURE 3 is a cross-sectional view taken along line 3-3 of FIGURE 1, except the apparatus is shown in the insertion configuration;

FIGURE 4 is similar to FIGURE 3, except the apparatus is shown with the cannula retracted and split;

FIGURE 5 is a cross-sectional view, rotated 90 degrees from the view of FIGURE 4;

FIGURE 6 is an enlarged view of a portion of FIGURE 3 showing the attachment of the cannula to the applicator;

FIGURE 7 is an enlarged view of a portion of FIGURE 4 showing the split cannula contained within the applicator;

FIGURE 8 is a cross-sectional view taken along line 8-8 of FIGURE 1;

FIGURE 9 is a cross-sectional view taken along line 9-9 of FIGURE 8;

FIGURE 10 is a perspective view of a cannula in accordance with the present invention;

FIGURE 11 is a cross-sectional view taken along line 11-11 of FIGURE 10;

FIGURE 12 is a cross-sectional view taken along line 12-12 of FIGURE 10;

FIGURE 13 is a perspective view of an alternate embodiment of apparatus in accordance with the present invention; and

FIGURE 14 is an illustration in partial cross section of an epidural or subdural catheter placement.

Detailed Description of the Preferred Embodiment

Referring now to the drawings wherein like reference numerals designate identical or corresponding parts throughout the several views, and more particularly to FIGURE 1, an apparatus for inserting a catheter through the body membrane of a person or an animal is designated generally by the numeral 20. Apparatus 20 includes a cannula 22 (see FIGURE 3), much in the form of a cannulated needle, and an applicator 24 for supporting a catheter 26 during placement through a body membrane, usually skin. Applicator 24 also serves as a container for cannula 22 before insertion of cannula 22 and catheter 26 through the body membrane and after retraction of the cannula therefrom.

Applicator 24 includes first, second and third members 28, 30, and 32, respectively, which interact with one another to achieve many of the advantages of the present invention. As shown more clearly in FIGURES 3-5, first member 28 is formed to have an outer barrel 34 with a first wall 36. Outer barrel 34 has an open first end 38 (see FIGURE 4) and a closed second end 40. Closed end 40 is

formed arcuately at end surface 42 for easy contact by the thumb of a doctor or nurse. First member 28 also includes a hollow splitter member 44 which is concentric with first wall 36 and is centered on axis 46 of applicator 24. Splitter member 44 extends from closed end 40 to beyond open end 38. The unattached end 46 of splitter member 44 is conically shaped in order to mate with the conical seat 98 of cannula 22.

Catheter 26 is essentially a flexible tube 54 having proximal and distal end portions 48 and 50. The proximal end portion 48 usually includes a standard Luer lock 52 or other connector which is attached to the flexible tube 54. As shown in FIGURE 8, it is often desirable to use a stylet 56 to extend through catheter 26 and provide some rigidity for flexible tube 54. First member 28 is formed to receive catheter 26. The cylindrical passage 58 in splitter member 44 has a diameter preferably slightly larger than the diameter of flexible tube 54. Passage 58 extends into closed end 40 of first member 28 wherein a cavity 60 of sufficient size to receive Luer lock 52 is formed. Cavity 60 opens through surface 42 to provide access to stylet 56. As shown in FIGURE 1, the proximal end of first member 28 is half missing in order to easily eject Luer lock 52 as described hereinafter.

Second member 30 is formed as an inner barrel 62 having an open third end 64 and a fourth end 66 with a passageway 68 formed therein. Inner barrel 62 has a second wall 70 which fits between the first wall 36 of outer barrel 34 and splitter member 44. More particularly, second wall 70 fits in close relationship with first wall 36 in a space sufficiently spaced from splitter member 44 to provide for tubular portion 108 of third member 32. Passageway 68 is centered on applicator axis 46 and has a diameter slightly greater than the diameter of tubular portion 84 of cannula 22.

Stablizing assembly 72 is attached near the distal end of second member 30. Stabilizing assembly 72 comprises a plurality of equally spaced-apart legs 74 extending outwardly from wall 70 to support a partial ring 76 which connects the legs 74, but is open between two of the legs 74 to provide a space for separating applicator 20 from catheter 26 as described hereinafter. The distal end surface 78 of inner barrel 62 extends slightly beyond the plane of outer surface 80 of ring 76 which is intended to contact the skin 82 and form a reference. End surface 78 extends beyond ring surface 80 to press down flesh which may be protruding upwardly as a result of a port, as shown, or as a result of flesh protruding upwardly within ring 76.

Description of third member 32 will be more clear if cannula 22 is first described. As shown in FIGURES 10-12, cannula 22 has a hollow, elongated tubular portion 84 with a distal end portion 86 and a proximal end portion 88. The distal end portion is sharpened to a point 90 to facilitate piercing any body membrane. Point 90 is shown to have a wedge-shape. It is understood, however, that other shapes are equally applicable, including the known Huber point which tends to minimize the capture of a core of tissue in tubular portion 84 when the body membrane is pierced. When cannula 22 is installed within applicator 20, the axis 92 of cannula 22 aligns with axis 46 of applicator 24.

As shown in FIGURE 11, tubular portion 84 includes a pair of separable joints which extend axially and facilitate the splitting of cannula 22. One of the separable joints is preferably a trough or groove 94 which is scribed or otherwise formed in the interior surface of tubular portion 84 before rolling tubular portion 84 or otherwise completing its fabrication. The other joint is preferably a slit 96 between the two edges of tubular portion 84 after it is rolled or otherwise formed into a tubular shape.

As shown in FIGURE 12, a conical seat 98 is formed in the interior proximal end of tubular portion 84. Conical seat 96 mates with the unattached cone-shaped end 46 of splitter member 44 when cannula 22 is installed in applicator 24. A pair of spaced-apart arms 100 extend from the formation of conical seat 98 diagonally outwardly from axis 92 and in a region 102 are bent so that the proximal end portions of arms 100 are parallel with one another. Arms 100 are preferably formed arcuately along their length and preferably have a curvature which is concentric with tubular portion 84. In this regard, the facing sides 104 of the parallel portions of arms 100 are spaced apart along any line through axis 92 a distance which is greater than the outer diameter of tubular portion 84 (see FIGURE 12). In this way, splitter member 44 is easily received between arms 100 so that its cone-shaped end 46 may fit in conical seat 98.

Near the proximal end of arms 100, each includes a barb 106 extending outwardly. Barbs 106 may be formed as a cantilevered member as shown in FIGURE 10 or may be formed in some other equivalent fashion, such as a protrusion from the wall of a solid arm. Barbs 106 serve to fasten cannula 22 to third member 32 as described hereinafter.

Third member 32 includes a tubular portion 108 with a pair of finger pieces 110 extending outwardly from opposite sides thereof. Tubular portion 108 fits between second wall 70 of inner barrel 62 and splitter member 44. As shown in FIGURES 6-8, the distal end 109 of tubular portion 108 includes passages 112 shaped and sized to receive arms 100 of cannula 22. Each passage 112 includes an indent 114 in the wall of the passage in order to receive a barb 106 of cannula 22. Passages 112 extend into the distal end 109 of tubular portion 108 sufficiently so that when apparatus 20 is in the pre-insertion configuration, barbs 106 are received in indents 114 and conical end 46 of splitter member 44 fits into conical seat 98 of cannula 22.

Each of finger pieces 110 has a planar neck 116 which fits through slots 118 and 120 on the opposite sides of first and second members 28 and 30, respectively. Otherwise, finger pieces 110 may have a greater thickness so as to be comfortable when held. As shown, one of finger pieces 110 is formed to receive a single finger, while the other finger piece 110 is formed to receive two fingers.

First, second and third members 28, 30 and 32, as well as splitter member 44, have an axial slot 122, 124, 126 and 128, respectively. Slots 122, 124, 126 and 128 allow applicator 24 to be separated from catheter 26 after cannula 22 has been split.

Applicator 20 also includes a first releasable locking mechanism 130 for locking first and third members 28 and 32 together and a second releasable locking mechanism 132 for locking first and second members 28 and 30 together. In addition, a locking pin 134 prevents applicator 20 from being functioned prematurely. First locking mechanism 130 comprises a flexible arm 136 attached at one end to neck 116 of one of the finger pieces 110. Arm 136 has an arcuate portion 138 which is adjacent to and substantially conforms to the curvature of outer barrel 34. The unattached end of arm 136 extends away from arcuate portion 138 in a direction approximately perpendicular with neck 116. End portion 140 extends outwardly sufficiently far so that the end 142 of slide pin 144 pushes against it through the full travel of slide pin 144. Arcuate portion 138 also includes a protrusion 146 which fits into an opening 148 in first wall 36 of first member 28 when applicator 20 is in its pre-insertion configuration. Since arm 136 is attached to third member 32 and since it engages first member 28, arm 136 functions to lock first and third members 28 and 32 together when protrusion 146 fits in opening 148.

Second locking mechanism 132 functions to releasably lock first and second members 28 and 30 together.

Second locking mechanism 132 includes an axially-extending, cantilevered arm 150 attached to wall 70 of inner barrel 62 at a location beyond the distal end of first wall 36 of outer rail 34 when first member 28 is at its nearest location to stabilizing assembly 72. Arm 150 is spaced just slightly outwardly from and conforms in the arcuate shape of wall 36. The outer side of arm 150 includes regularly spaced grooves 154 oriented perpendicular to axis 46 and formed from one end of arm 150 to the other. Arm 150 extends toward the proximal end of applicator 24 sufficiently far so that it may always be engaged by slide lock 144 regardless of the relative location of first and second members 28 and 30. Near the bottom of first wall 36, a housing 156 extends outwardly in order to support slide lock 144. Slide lock 144 is a flat pin 158 with a head 160. Head 160 is shaped arcuately for a comfortable fit with a person's finger. Slide lock 144 is oriented so that pin 158 is perpendicular with respect to axis 46 in a dimension parallel with finger pieces 110. Housing 156 includes slots 162 on opposite sides thereof for receiving slide lock 144. Slide lock 144 has three sets 164, 166 and 168 of small protrusions on the opposite axially-spaced-apart sides of slide lock 144. In addition, at a set back distance from end 142, slide lock 144 includes a plurality of grooves 170 for mating with and engaging grooves 154. When protrusions 164 and 166 hold slide lock 144 on opposite sides of housing 156 in order to prevent slide lock 144 from inadvertently moving in either direction, end 142 is adjacent to end portion 140 of arm 136 and grooves 170 are disengaged with respect to grooves 154. When slide lock 144 is pushed with a finger at head 160, protrusions 166 are forced through one of slots 162 and slide lock 144 moves until set of protrusions 168 contacts a wall of housing 156. In this configuration, grooves 170 and 154 are engaged and end 142 has moved arm 136 so that protrusion 146 is disengaged from opening 148.

Locking pin 134 extends between outer barrel 62 and slide lock 144 on the side of applicator 24 opposite from arm 136. Openings 172 and 174 in neck 116 and slide lock 144, respectively, receive locking pin 134. In addition, locking pin 134 is located to pass through first and second walls 36 and 70 so as to lock first, second and third members 28, 30 and 32 with respect to one another and prevent premature functioning. Head 176 stops pin 134 with respect to first wall 36 while protrusions 178 hold pin 134 in place with respect to opening 174. A slot 180 in the end of pin 134 opposite head 176 provides for compression of pin 134 in the region of protrusions 178 for easy removal of pin 134 when desired.

The various parts described interrelate with one another to provide a pre-insertion configuration as shown in FIGURES 1, 2, 8 and 9; an insertion configuration as shown in FIGURES 3 and 6; and a retraction configuration as shown in FIGURES 4, 5 and 7. In the pre-insertion configuration, cannula 22 is completely contained within barrels 34 and 62. Outer barrel 34 and inner barrel 62 are sufficiently long so that inner barrel 62 fits somewhat inside outer barrel 34, enough so that when relative movement between the two is necessary, binding does not occur. Finger pieces 110 are approximately aligned with housing 156 so that locking pin 134 can extend between a neck 116 of one of finger pieces 110 and slide lock 144. The distal ends of first, second and third members 28, 30 and 32 are related such that cannula 22 is received in passages 112 of tubular portion 108 while tip 90 of cannula 22 does not extend through passageway 68 of second member 30. In addition, cone-shaped end of splitter member 44 is in contact with conical seat 98 of cannula 22.

A depth indicating or monitoring system 182 for apparatus 20 is illustrated in FIGURE 1. A series of axially extending, regularly spaced markings 184 is inscribed along

inner barrel 62. A window 186 is formed near the distal end of outer barrel 34. A scribe line 188 on outer barrel 34 matches with the markings 184 and numbers associated therewith to indicate a depth of insertion. When the "0" 184 matches with line 188, point 90 of cannula 22 is in the plane of surface 78 of stabilizing assembly 72. An insertion depth of "8" is shown in FIGURES 3 and 4.

In the insertion configuration, locking pin 134 is removed. Third member 32 functions as a moving mechanism for cannula 22 and first member 28. As third member 32 is moved toward the reference surface 80 of stabilizing assembly 72, the distal ends of cannula 22 and catheter 26 pass through passageway 68 to extend beyond the distal end of inner barrel 62. Slots 120 in inner barrel 62 extend sufficiently toward the distal end of inner barrel 62 so that when necks 116 contact the distal ends of slots 120, the insertion depth will be the maximum allowed for apparatus 20, that is, index numeral "12" for indicating system 182. It is understood that insertion can be made to any desired depth between numerals "0" and "12". It is also noted that slot 118 extends to the open end of outer barrel 34.

In the retraction configuration, slide lock 144 is moved so that grooves 154 and 170 engage and arm 136 is bent to disengage protruberance 146 from opening 148. First and second members 28 and 30 are now locked together, while third member 32 is free to move relative thereto. When third member 32 is moved toward the proximal end of applicator 24, cannula 22 is split as it is forced against splitter member 44. During this operation, conical seat 98 functions to guide the cone shaped end 46 of splitter member 44 into tubular portion 84 to split cannula 22 along slit 96 and groove 94. As shown in FIGURE 7, the split cannula 22 is received in space between second wall 70 of inner barrel 62 and splitter member 44. Third member 32 is moved toward the

proximal end of first member 28 until the proximal end of tubular portion 108 contacts the closed end 40 of inner barrel 34. As tubular portion 108 approaches closed end 40, a post-like extension 190 extends from the proximal end of tubular portion 108 to contact Luer lock 52 and eject it outwardly from first member 28 thereby beginning the separation of catheter 26 from applicator 34 as depicted in FIGURE 5. Extension 190 is integral with tubular portion 108, but protrudes outwardly from the outer diameter of tubular portion 108 to locate within the same cylindrical envelope as inner barrel 62. In the final retraction configuration, Luer lock 52 is ejected outwardly and cannula 22 is split so that it is now a simple task to move flexible tube 50 through slots 128, 126, 124 and 122 to separate catheter 26 from cannula 22 and applicator 24.

To use, locking pin 134 is removed to free apparatus 20 so that it may be functioned to move from the pre-insertion configuration to an insertion configuration. During such movement, protrusion 146 on arm 136 engages opening 148 so that first member 28 and third member 32 move together with respect to second member 30 and the reference surface 80 is established by stabilizing mechanism 72 which is attached to second member 30. Apparatus 20 is then situated on the person or animal so that stabilizing assembly 72 is placed as desired to provide the appropriate stabilization and reference for inserting cannula 22 and catheter 26 through the desired body membrane. Although it is understood that insertion may occur with respect to any body membrane which can be accessed from outside the body, usually the body membrane of interest will be the skin of the person or animal. Applicator 24 is then grasped with two or three fingers at finger pieces 110. Pressure is applied to move third member 32 toward the reference thereby penetrating and inserting the distal ends of the cannula and the catheter

contained therein through the body membrane. Since a reference is established with the stabilizing assembly 72, the depth of insertion may be monitored and stopped whenever an appropriate depth is sensed. The depth indicating mechanism shown in FIGURE 1 is visual. It is understood, however, that other systems can also be used, for example, a ball with a series of detents that can be heard or felt as relative movement occurs.

After insertion has been made to a desired depth, the cannula is retracted. More particularly, slide lock 144 is moved so that grooves 154 and 170 engage one another and protruberance 146 of arm 136 is forced to disengage from opening 148. In this configuration, first and second members 28 and 30 are locked together, while third member 32 may move relative thereto. With a thumb or other restraint on end surface 42 of first member 28, third member 32 is moved toward the proximal end of applicator 24 with fingers pulling finger pieces 110 toward end surface 42. As this occurs, cannula 22 is retracted, while catheter 26 remains inserted. In order to provide some rigidity for flexible tube 50 of catheter 26, a stylet 56 may be present in catheter 26. As conical seat 98 is forced against the cone-shaped end 46 of splitter member 44, tubular portion 84 is forced to separate at slit 96 and groove 94 thereby splitting tubular portion 84. As cannula 22 is retracted into applicator 24, it is bent in region 102 and in a region near conical seat 98 to be received between inner barrel 62 and splitter member 44 as shown in FIGURE 7. Third member 32 is moved with respect to first member 28 until the proximal end of tubular portion 108 contacts closed end 40 and protruberance 146 engages opening 194. As this occurs, ejector extension 190 contacts Luer lock 52 and forces it outwardly. Catheter 26 may now be separated from apparatus 20 by moving it through split cannula 22 and slots 128, 126, 124 and 122. Apparatus 20 may now be disposed of. Catheter 26 remains in an inserted pla-

cement with respect to the body membrane of the person or animal.

As indicated, apparatus 20 may be used to insert a catheter through a variety of body membranes. For example, insertion may occur for such placements as transcutaneous, intraportal, epidural, intraveneous, intra-arterial, intramuscular, subcutaneous, intratecal, intracerebroventriular, stereotactic, or into any specific body site or chamber. FIGURES 3-5 illustrate the use of apparatus 20 with respect to an intraportal placement. With the stablization assembly 72, an intraportal placement use is particularly advantageous. It is noted that once the port has been surgically implaced that a measurement can be made between the skin and the cavity within the port. Repetitive insertions of a catheter with apparatus 20 may then be easily made to a desired depth by observing the depth indicating system 182.

In FIGURE 10, use of apparatus 20 is shown with respect to an intravascular placement where the catheter is placed to generally align with the direction of a vein or artery. An alternate embodiment of a stabilizing assembly 196 is shown. Stablizing assembly 196 is an arcuate member having the general curvature of the extremity. The arcuate member is attached to the distal end of inner barrel 62.

An epidural placement is shown in FIGURE 14 whereby the catheter remains in place, while apparatus 20 has already been separated therefrom and disposed of.

Accordingly, the preferred embodiment of apparatus in accordance with the present invention has been described with particularity. It is understood, however, that equivalencies in structure and function are possible. Consequently, it is understood that changes made, especially in matters of shape, size and arrangement to the full extent extended by the general meaning of the terms in which the appended claims are expressed, are within the principle of the invention.

WHAT IS CLAIMED IS:

1. Apparatus for inserting a catheter through a body membrane of a person or an animal, comprising:

means for supporting said catheter during insertion of a portion of said catheter through said membrane, said supporting means including a pointed cannula for piercing said membrane, and

means for stabilizing said supporting means with respect to said membrane.

2. Apparatus in accordance with claim 1 wherein said stabilizing means establishes a reference and said appartus further includes means for monitoring depth of insertion relative to said reference.

3. Apparatus in accordance with claim 1 wherein said supporting means and said stablizing means together include means for separating said catheter from said apparatus after said catheter has been inserted through said membrane.

4. Apparatus in accordance with claim 3 wherein said separating means includes means for splitting said cannula on retraction of said cannula from said person or animal.

5. Apparatus for inserting a catheter through a body membrane of a person or an animal, said catheter having proximal and distal end portions, said apparatus comprising:

a splittable cannula for receiving the proximal end portion of said catheter, said cannula extending between proximal and distal ends, said distal end of said cannula being sharpened to pierce said membrane;

means for containing said cannula before insertion of the distal ends of said cannula and said catheter through said membrane and after retraction of said cannula from said

person or animal, said containing means including a passageway through which said catheter and said cannula move during insertion, said containing means also including means for splitting said cannula;

means connected to said containing means for moving said cannula with respect to said passageway so that said cannula and said catheter may be advanced during insertion and for moving said cannula against said splitting means on retraction; and

means for separating said catheter from said cannula, said containing means and said moving means after splitting said cannula.

6. Apparatus in accordance with claim 5 wherein said splitting means includes a splitter member with a conically shaped end for fitting in the proximal end of said cannula to split said cannula apart as said cannula is moved by said moving means against said conically shaped end.

7. Apparatus in accordance with claim 5 wherein said containing means includes a first member forming at least partially an outer barrel with an open first end, said outer barrel having an axis, said splitting means being attached to said outer barrel and being centered on said axis, said containing means further including a second member forming at least partially an inner barrel having an open second end, said inner barrel having a wall which fits between said outer barrel and said splitting means, said passageway being formed in said inner barrel and centered on said axis, whereby said first and second members may be moved with respect to one another during insertion or retraction.

8. Apparatus in accordance with claim 7 wherein said moving means includes a third member forming at least a par-

tial tube fitting between said inner barrel and said splitting means, said third member also including a finger piece attached to said tube for moving said tube with respect to one of said first and second members.

9. Apparatus in accordance with claim 8 wherein said cannula includes a pair of spaced-apart arms with a barb near the free end of each of said arms, said tube of said moving means including passages for receiving said arms, said passages having walls, said attaching means further including an indent in the wall of each of said passages for receiving one of said barbs thereby holding said cannula with respect to said moving means.

10. Apparatus in accordance with claim 8 wherein said first, second and third members include first, second and third slots, respectively, said first, second and third slots being aligned with one another so that when said cannula is split on retraction, said catheter may be removed from said apparatus through said slots.

11. Apparatus in accordance with claim 10 wherein said partial tube of said third member includes means for ejecting the proximal end portion of said catheter from said apparatus.

12. A cannula for use with an applicator for inserting a flexible catheter through a body membrane of a person or an animal, said applicator including a tubular-like element with an unattached cone-shaped end, said cannula comprising:

a member having a hollow, elongated tubular portion with a distal end portion and a proximal end portion, the distal end portion of said tubular portion being sharpened to facilitate piercing said membrane, said tubular portion having an axis, said tubular portion also having a plurality

of axially extending separable joints, said tubular portion having a proximal end, the proximal end of said tubular portion forming a conical seat for receiving the unattached cone-shaped end of the tubular-like element of said applicator, the proximal end portion extending from said conical seat to form means for connecting said member to said applicator, whereby movement of said tubular-like element of said applicator with respect to said cone-shaped seat into said tubular portion of said cannula of said cannula causes said tubular portion to split at said separable joints for easy removal of said catheter from said cannula.

13. A cannula in accordance with claim 12 wherein said tubular portion of said member has an outer side with a diameter and said connecting means includes a pair of spaced-apart arms extending from said conical seat and having facing sides with parallel portions spaced along any line through said axis a distance greater than said diameter.

14. Apparatus in accordance with claim 13 wherein said connecting means further includes a barb extending outwardly from each of said arms to engage said applicator.

15. Apparatus for inserting a catheter through a body membrane of a person or an animal, comprising:

an applicator; and

a cannula having a hollow, elongated tubular portion for receiving a portion of said catheter, said cannula having a distal end portion and a proximal end portion, the distal end portion of said tubular portion being sharpened to facilitate piercing the membrane of said person or animal, said tubular portion having an axis, said tubular portion also having a plurality of axially extending separable joints, said tubular portion further having a proximal end,

the proximal end of said tubular portion forming a conically walled seat, the proximal end portion of said cannula extending from said conical seat to form means for connecting said cannula to said applicator;

said applicator including means for splitting said cannula along said separable joints, said splitting means including a hollow, tubular-like element with an unattached cone-shaped end, said cone-shaped end mating with said conical seat, said applicator further including means for moving said cannula with respect to said tubular-like element;

whereby after insertion of said flexible catheter through the membrane of said person or animal, movement with said moving means of said cannula with respect to said tubular-like element from said cone-shaped seat into said tubular portion of said cannula causes said tubular portion to split at said separable joints for easy removal of said catheter from said cannula.

16. Apparatus for inserting a catheter through a body membrane of a person or an animal, said catheter having proximal and distal end portions, said apparatus comprising:

a cannula having a hollow, elongated tubular portion for receiving said catheter, said cannula extending between a distal end portion and a proximal end portion, the distal end portion of said tubular portion being sharpened to facilitate piercing said skin, said tubular portion having an axis, said tubular portion also having a plurality of axially extending separable joints, said tubular portion having a proximal end, the proximal end of said tubular portion forming a conical seat, the proximal end portion of said cannula extending from said conical seat to form a plurality of spaced-apart arms;

a first member forming an outer barrel having a first wall with an open first end and a closed second end,

said first member including a hollow splitter member centered on said axis and extending from said closed second end, said splitter member having an unattached, conical end to mate with said conical seat of said cannula;

a second member forming an inner barrel having an open third end and a fourth end with a passageway formed therein, said inner barrel having a second wall which fits between said first wall of said outer barrel and said splitter member, said passageway being centered on said axis;

means, attached to said second barrel, for stabilizing said second barrel with respect to the membrane of said person or animal;

a third member including a tubular portion fitting between the second wall of said inner barrel and said splitter member, said third member including a finger piece attached to said tubular portion for moving said tubular portion with respect to at least one of said first and second members, said tubular portion further including passages for receiving said plurality of arms of said cannula;

means for fastening said arms of said cannula to said tubular portion of said third member;

first, second and third slots in said first, second and third members, respectively, and a fourth slot in said splitter member, said slots being aligned with one another so that when said cannula is split said catheter may be removed from said apparatus through said slots;

first means for releasably locking said first and third members together; and

second means for releasably locking said first and second members together;

whereby when said second and third members are locked together with said first locking means, said cannula may be inserted through the membrane of said person or animal with said second member being held with respect to the membrane by said stabilizing means, and when said first and

second members are held together with said second locking means, said third member may move said cannula against said splitter member to split said cannula along said separable joints so that said catheter may be removed through said slots thereby separating said apparatus from said catheter which remains extending through the membrane of said person or animal.

17. A method for using a cannula connected to an applicator to insert a catheter through a body membrane of a person or animal, a portion of said catheter fitting within said cannula, said cannula and said catheter having distal and proximal ends, the proximal end of said cannula being held by said applicator, said applicator including means for moving said cannula, said applicator further including means for stablizing said moving means with respect to said membrane, said method comprising the steps of:

placing said stablizing means on said person or animal;

inserting the distal ends of said cannula and said catheter through said membrane by moving said cannula with said moving means;

retracting said cannula from said person or animal; and

separating the catheter from said cannula and said applicator, thereby leaving said catheter extending through said membrane.

18. The method in accordance with claim 17 wherein said inserting step includes controlling insertion depth of said cannula and said catheter with respect to a reference established by said stablizing means, said applicator including means for monitoring insertion depth.

19. A method of using a cannula attached to an applicator for inserting a catheter through a body membrane of a person or animal, a portion of said catheter fitting within said cannula, said cannula and said catheter having distal and proximal ends, said applicator including means for moving said cannula, the proximal end of said cannula being connected to said moving means, said applicator also including means for stablizing said moving means with respect to said membrane, said applicator further including means for splitting said cannula on retraction of said cannula, said applicator still further including first means for locking said moving means with respect to said splitting means and second means for locking said splitting means with respect to said stablizing means, said method comprising the steps of:

placing said stablizing means on said person or animal, said first locking means being engaged;

inserting the distal ends of said cannula and said catheter through said membrane by moving said cannula with said moving means;

unlocking said first locking means to release said splitting means with respect to said moving means and locking with said second locking means said splitting means with respect to said stablizing means;

retracting said cannula from said person and moving said cannula with said moving means against said splitting means to split said cannula; and

separating said catheter from said cannula and said applicator, thereby leaving said catheter extending through said membrane.

20. The method in accordance with claim 19 wherein said inserting step includes controlling insertion depth of said cannula and said catheter with respect to a reference established by said stabilizing means, said applicator including means for monitoring insertion depth.

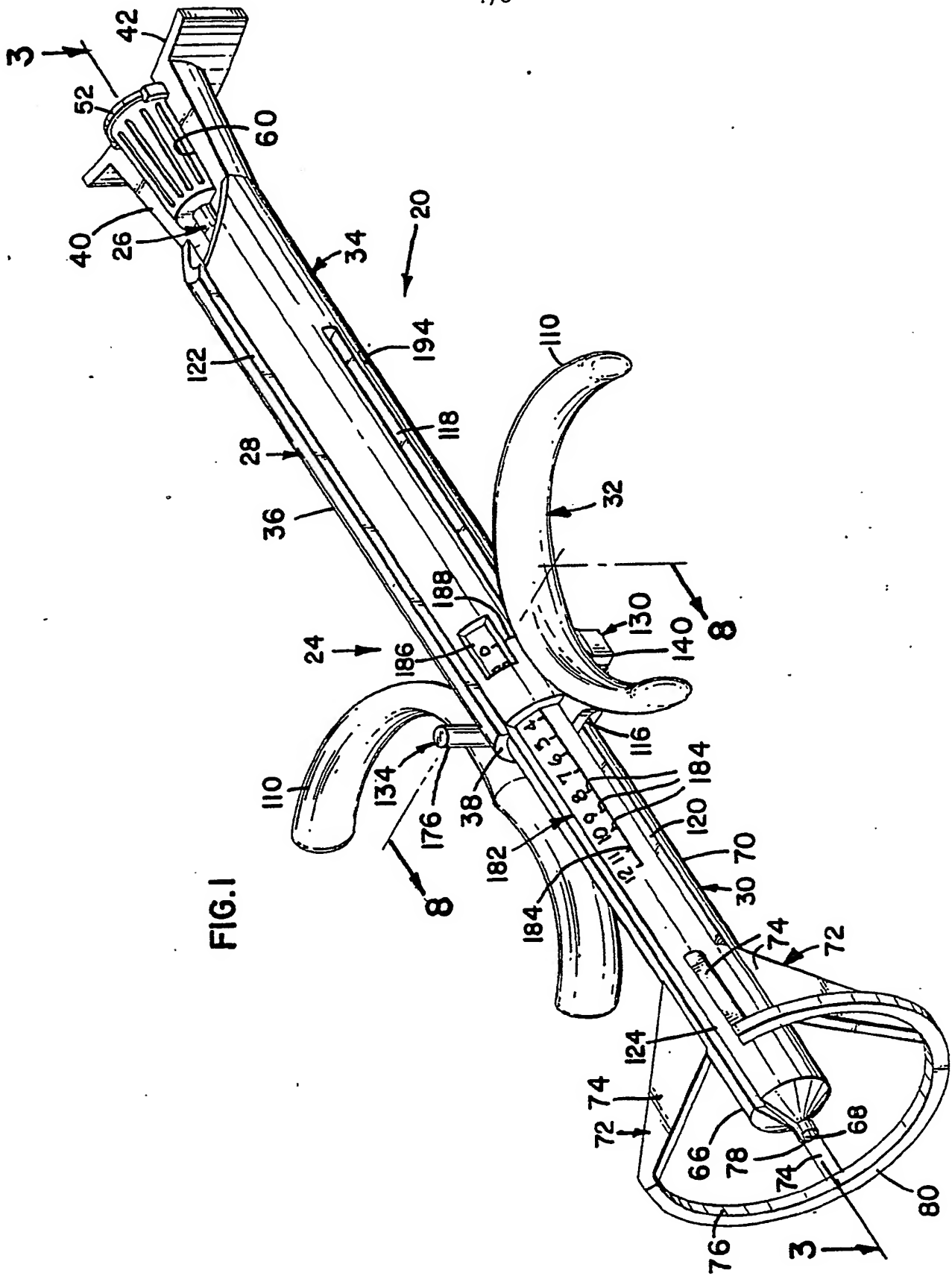
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FIG.1

FIG. 3

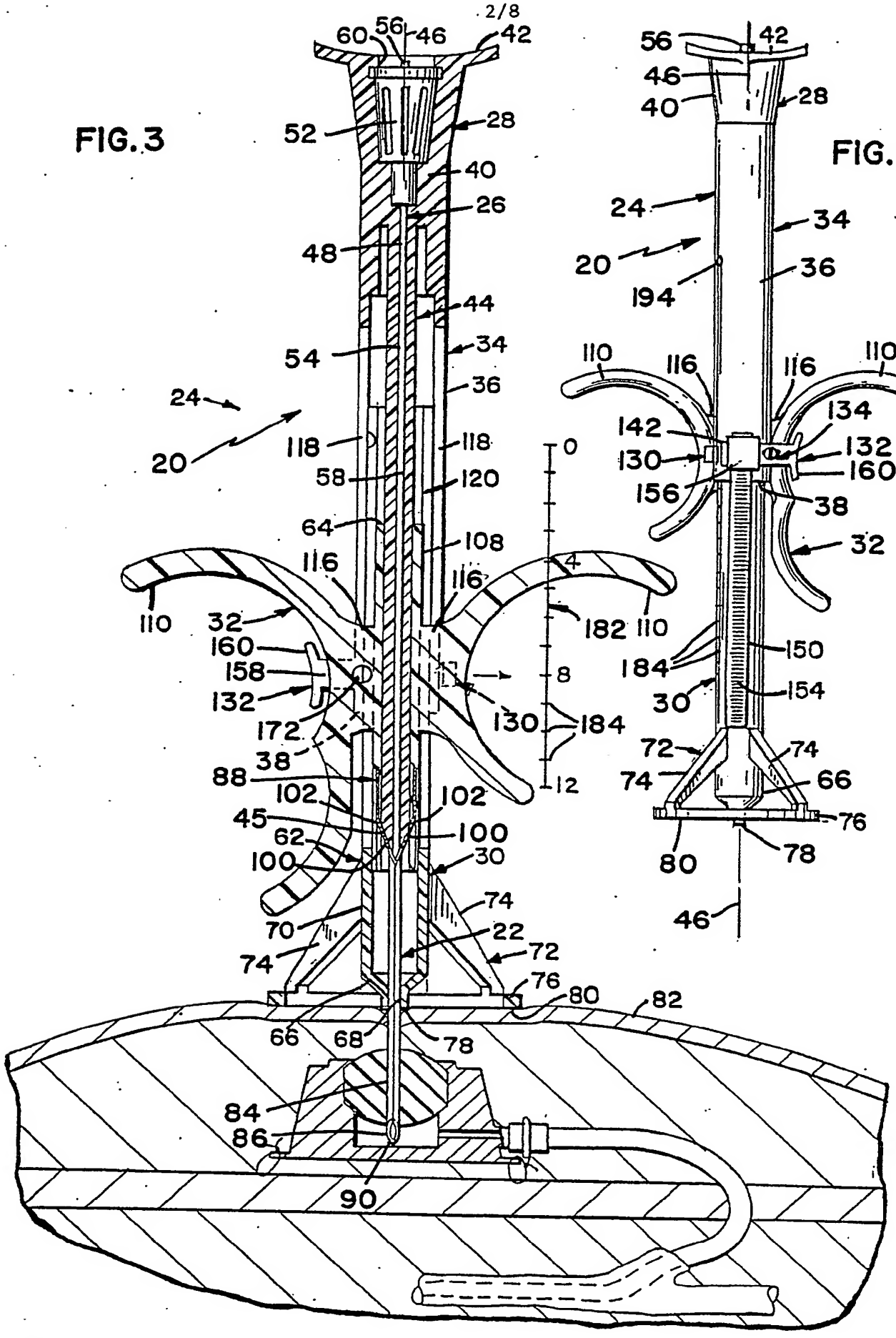
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FIG. 2

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FIG. 4

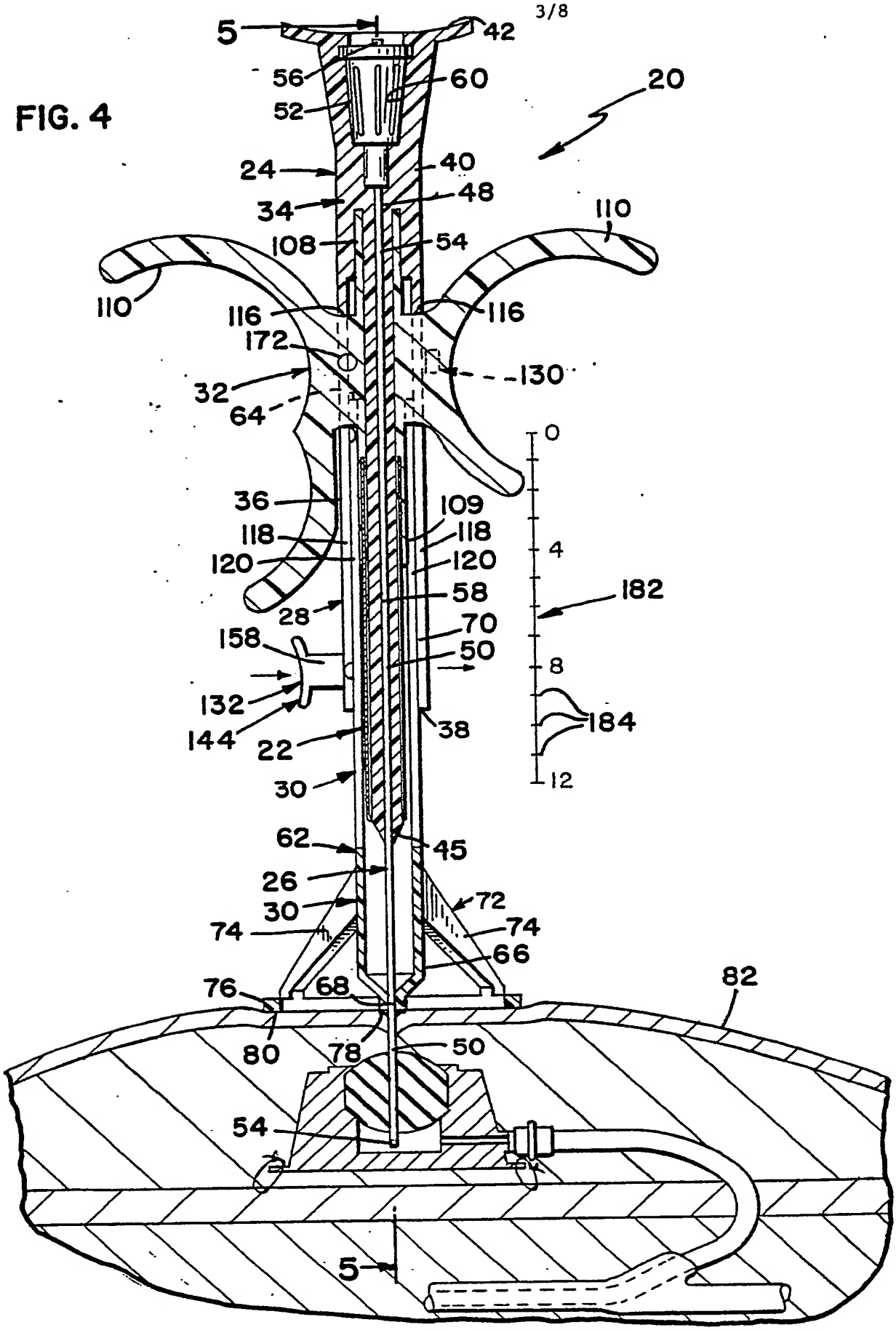
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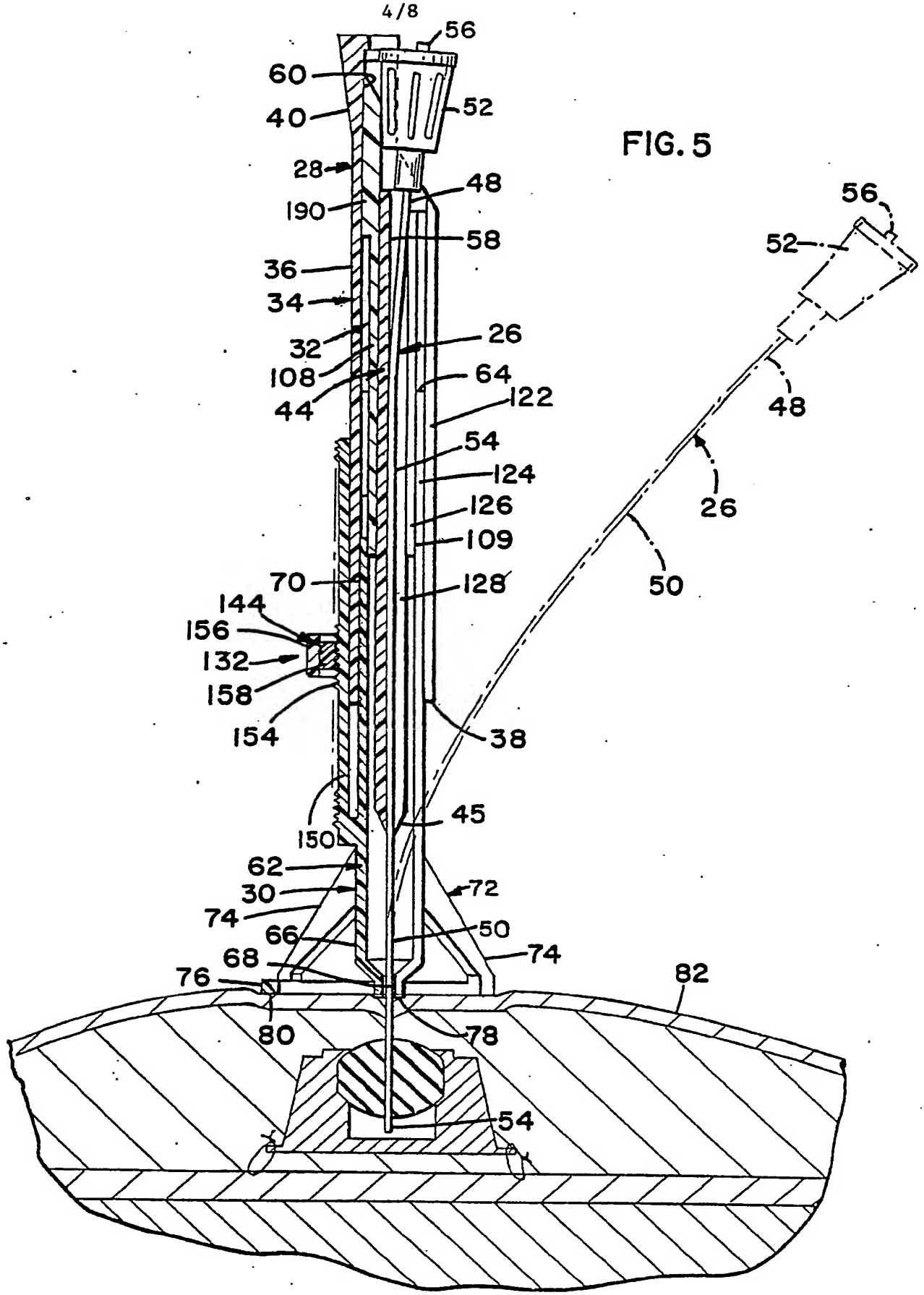
FIG. 5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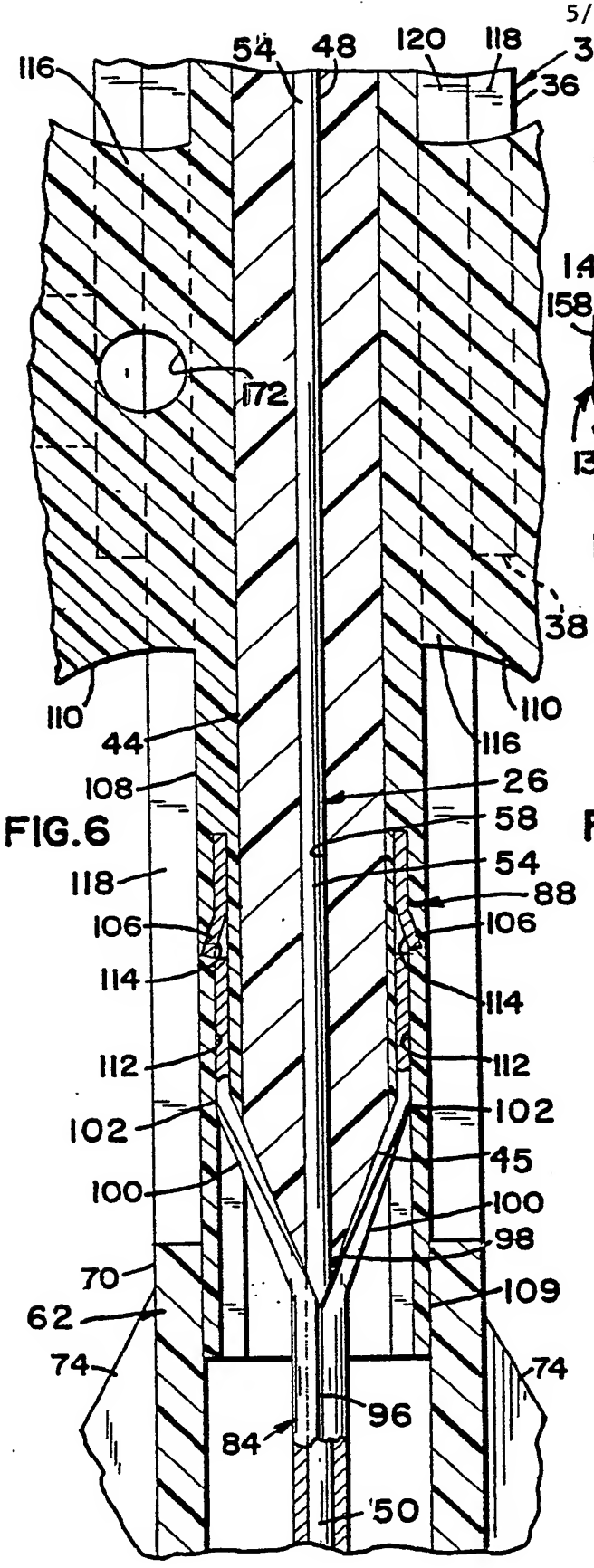
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FIG.6

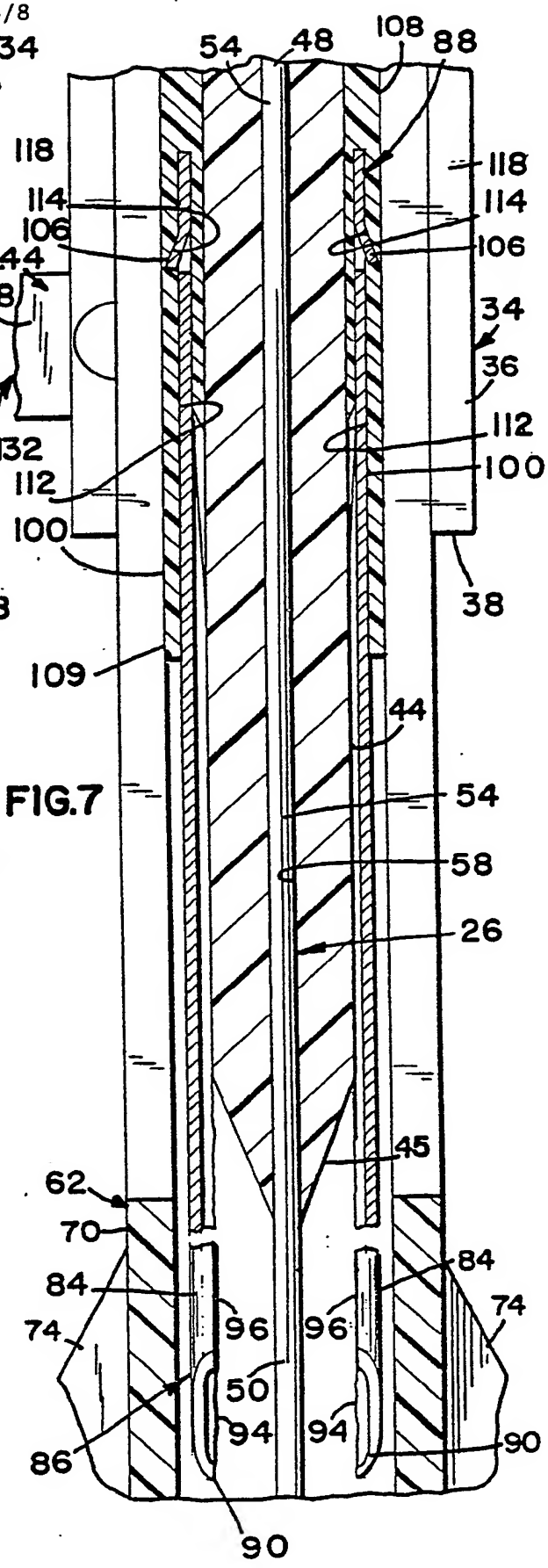
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FIG.7

FIG. 8

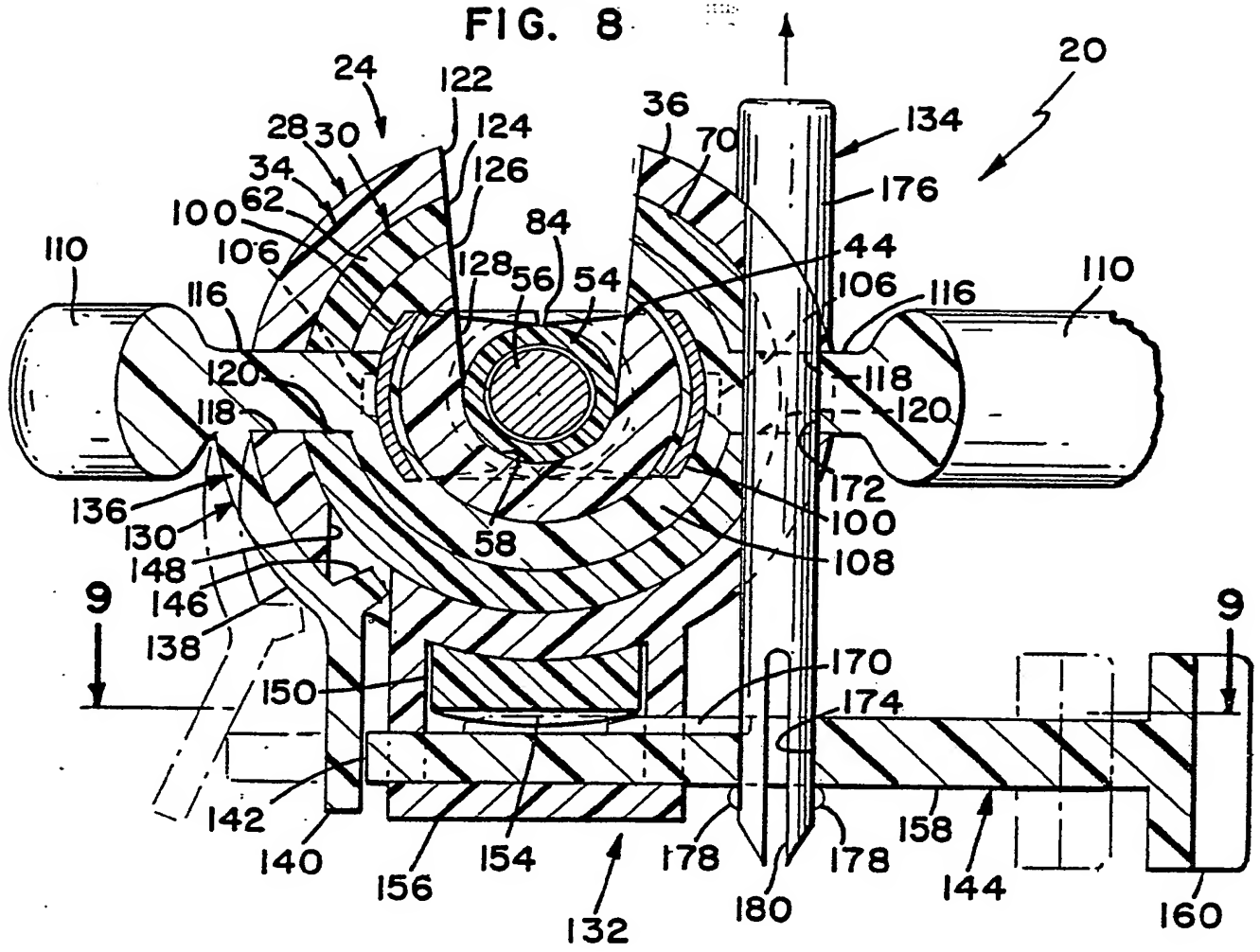
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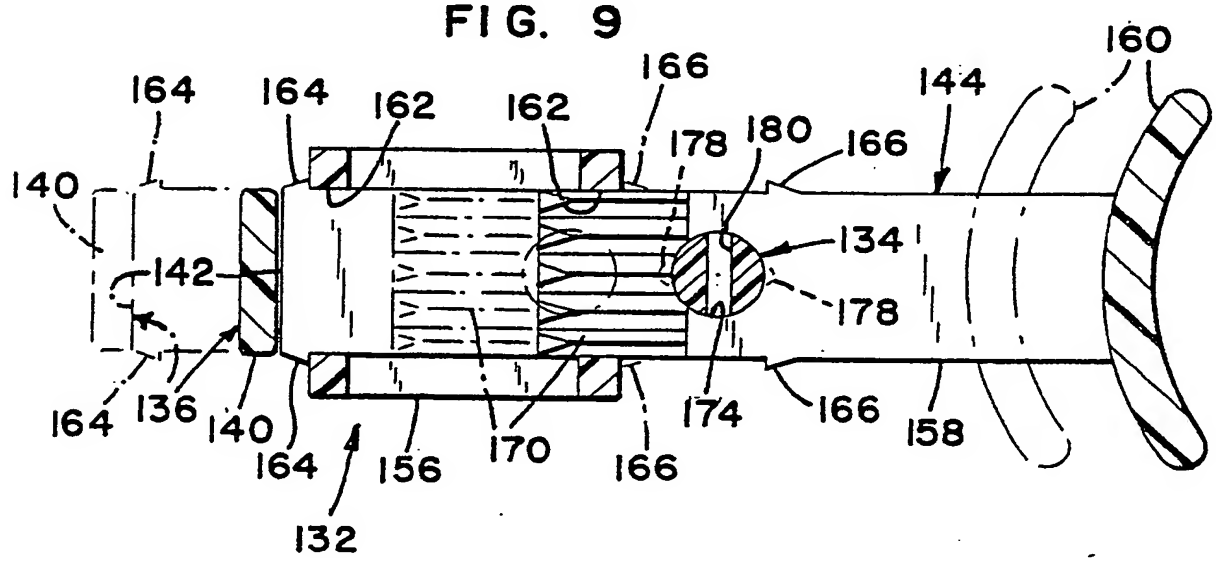
FIG. 9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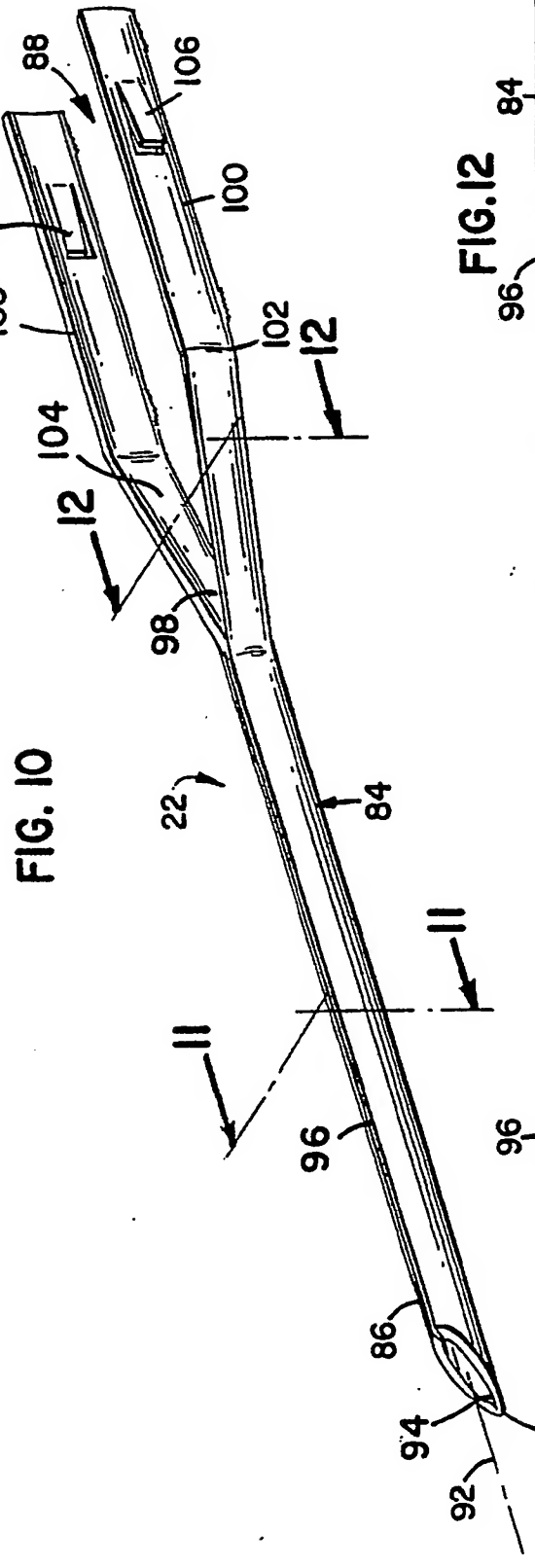

FIG. 10

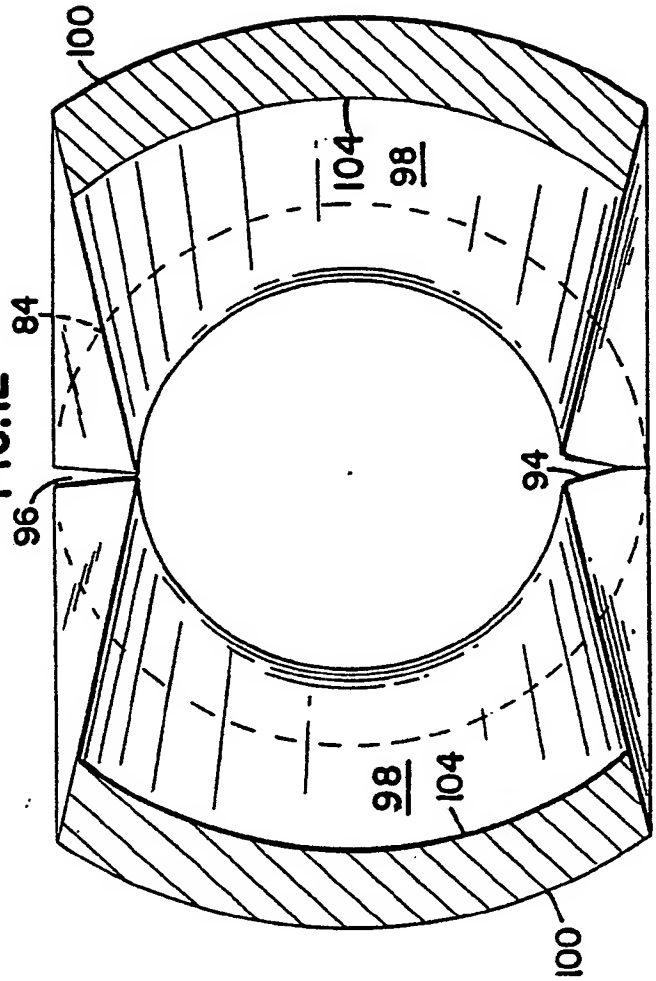

FIG. 12

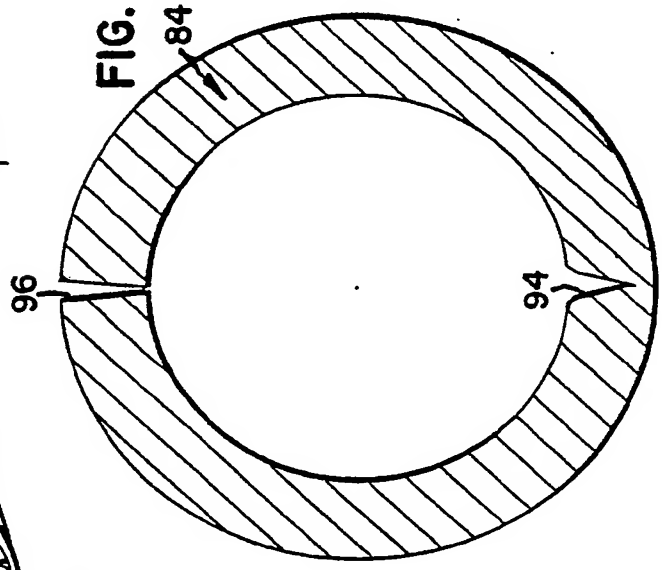

FIG. 11

FIG. 14

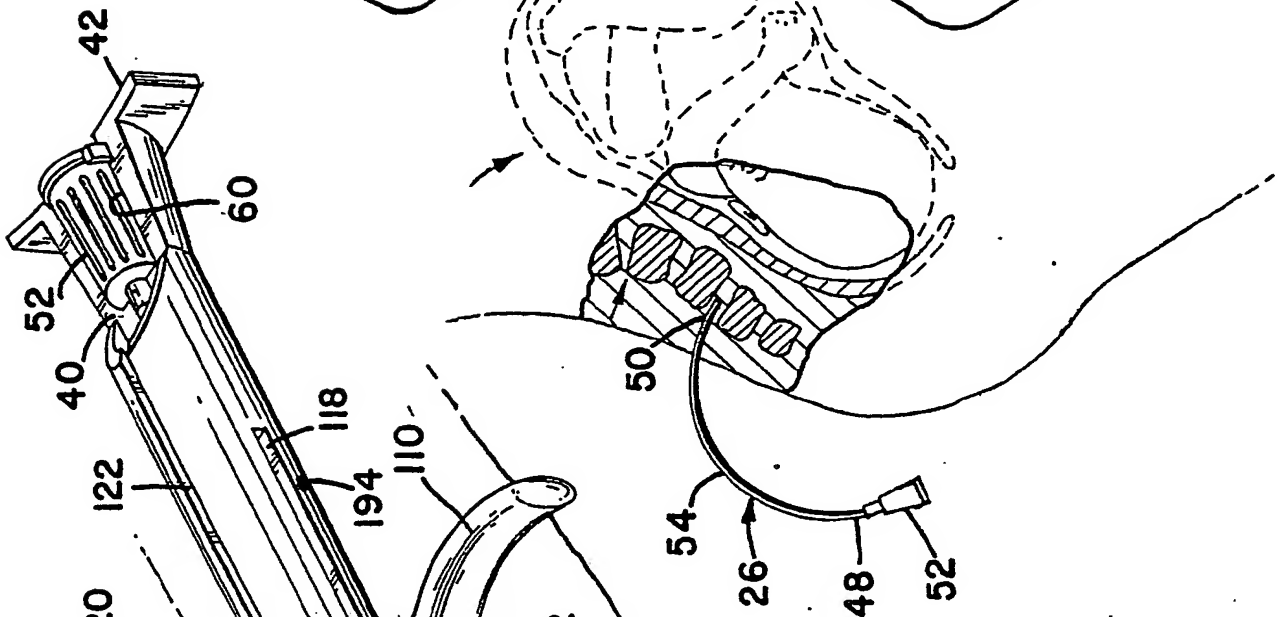
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FIG. 13

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A61M 25/00	A3	(43) International Publication Date: 5 May 1988 (05.05.88)

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(33) Priority Country: US

(71) Applicant: TITAN MEDICAL, INC. [US/US]; 1492 Brenner Avenue, Roseville, MN 55113 (US).

(72) Inventors: KOENIG, Marvin, E., Jr. ; 1492 Brenner Avenue, Roseville, MN 55113 (US). WILLIAMS, Jeffrey, M. ; 2375 Pinewood Circle, Mounds View, MN 55432 (US).

(74) Agent: HAMRE, Curtis, B.; Merchant, Gould, Smith, Edell, Welter & Schmidt, 1600 Midwest Plaza Building, Minneapolis, MN 55402 (US).

(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), DK, FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), SE (European patent).

Published

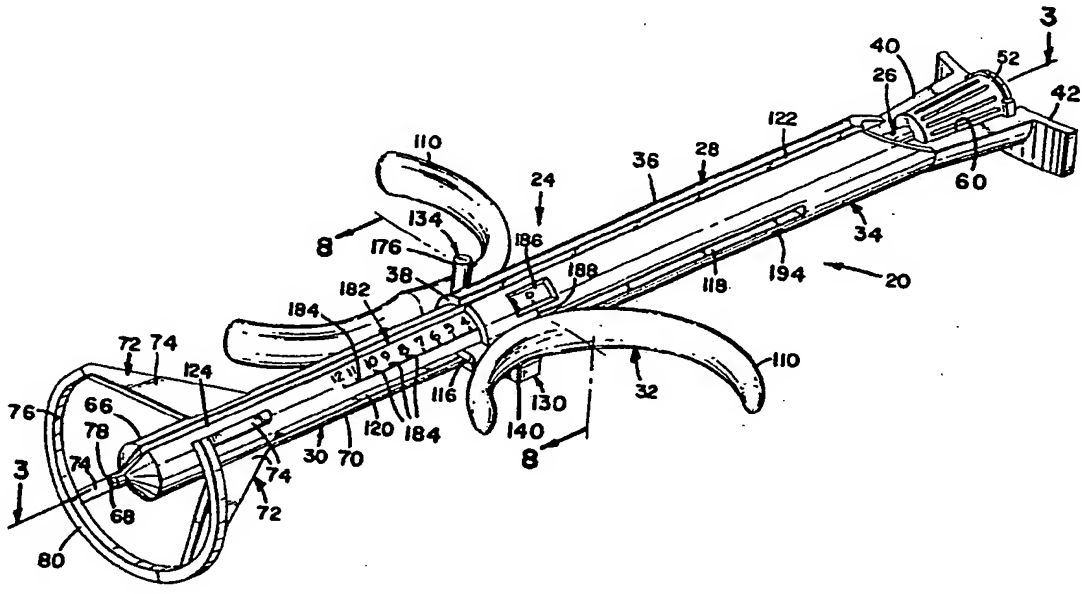
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(88) Date of publication of the international search report:

2 June 1988 (02.06.88)

(54) Title: APPLICATOR WITH SPLITTABLE CANNULA FOR PLACEMENT OF FLEXIBLE CATHETER



(57) Abstract

The applicator (24) combined with a splittable cannula (22) functions to place a catheter (26) through a body membrane and then separate from the catheter (26) leaving the catheter in place and allowing for disposal of the applicator and cannula. The catheter is supported during placement. The cannula is completely contained within the applicator except when the distal end is inserted through the body membrane. Depth of insertion is readily monitored.

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INTERNATIONAL SEARCH REPORT

International Application No PCT/US 87/02847

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 M 25/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	EP, A, 0155331 (TOYE) 25 September 1985 see figures 1-12 --	1-5
Y	US, A, 4352354 (UJIHARA) 5 October 1982 see figure 1 --	1-5
A	DE, A, 2855502 (PFM PLASTIK) 3 July 1980 see figures 1,2 --	1
A	EP, A, 0093101 (LINDER et al.) 2 November 1983 see figures 3,4 --	4,6,12
A	EP, A, 0125843 (CATHETER TECHNOLOGY) 21 November 1984 see figures 1,4 --	1-7
A	EP, A, 0021446 (INTERMEDICAT) 7 January 1981 see figure 1 --	4
A	US, A, 3262449 (PANNIER et al.) 26 July 1966 cited in the application	

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
30th March 1988	04. 05. 88
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	P.C.G. VAN DER PUTTEN

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International Application No. PCT/US 87/02847

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	US, A, 3359978 (SMITH) 26 December 1967 cited in the application	
	--	
A	US, A, 4449973 (LUTHER) 22 May 1984 cited in the application	
	--	
A	EP, A, 0067260 (LUTHER) 22 December 1982 cited in the application	

V. [X] OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. [X] Claim numbers 17-20 because they relate to subject matter not required to be searched by this Authority, namely:

See PCT Rule 39.1(iv)
Methods for treatment of the human or animal body by means of surgery or therapy as well as diagnostic methods.

2. [ ] Claim numbers ....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claim numbers ....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. [ ] OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. [ ] As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

[ ] The additional search fees were accompanied by applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 8702847 SA 19912

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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A- 0155331	25-09-85	US-A-	4471778	18-09-84
		EP-A,B	0052483	26-05-82
		US-A-	4364391	21-12-82
		CA-A-	1182022	05-02-85
US-A- 4352354	05-10-82	None		
DE-A- 2855502	03-07-80	None		
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US-A- 3262449		None		
US-A- 3359978		None		
US-A- 4449973	22-05-84	None		
EP-A- 0067260	22-12-82	JP-A-	57203452	13-12-82
		US-A-	4377165	22-03-83
		CA-A-	1173714	04-09-84

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